Attorney Docket No. 10124/01201

REMARKS

Claims 2, 7 and 10 have been canceled and claims 1, 3, 5, 13, 14, 16 and 17 have been amended. Claims 19 - 27 have been withdrawn from consideration.. No new matter has been added. Thus, claims 1, 3 - 6, 8, 9 and 11 - 18 are now in the present application. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are in condition for allowance.

The drawings stand objected to under 37 CFR 1.83(a). In support of the objection, the Examiner stated that the features: a first element guide, a sampling element actuator, a sampling safety lock, identification markings and an in-vivo tissue characterization device are not shown.

The Applicants respectfully disagree. A first element guide is shown in Fig. 1 as a placeholder element 104, and is further supported by at least paragraphs [0018] and [0019]. The feature, a sampling safety lock, is shown in Fig. 2 as needle lock 204. The id-markings are shown in Fig. 5 as color coded or numbered tags 420. As clarified by the amendment to claim 13, the recited in-vivo tissue characterization device, is actually an in-vivo tissue *treatment* device shown as a tissue treatment element 108 in Fig. 1. Thus, it is respectfully submitted that no amendments to the drawings are needed and it is respectfully requested that the objection to the drawings be withdrawn.

Claims 3 , 4, 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for containing subject matter which was not described in the specification. The Examiner asserted, in support of this rejection, that the disclosure does not describe a sampling element actuator and a sampling safety lock as recited in claims 3 and 4 or the first and second placeholder elements, identification markings and in-vivo tissue characterization device recited in claims 6 and 13.

It is respectfully submitted that the sampling element actuator recited in claim 3 is shown in Fig. 2 as the needle cutter actuator 206 described in paragraphs [0014] and [0015] and the sampling safety lock recited in claim 4 is shown in Fig. 2 as the safety 202 and the needle lock 204 and described in paragraphs [0014] and [015].

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Claims 6 recites first and second placeholder elements comprising identification markings. Paragraph [0020] of the specification states that:

> [M]eans to identify the various placeholder needles 410 used in the course of a procedure may be provided. For example, each placeholder needle 410 may include a color coded or numbered tag 420 to more easily relate the various biopsy samples obtained in a procedure to the locations at which tissue treatment or other treatments may be needed. Each of the placeholder needles 410 may also include a friction ring 416 to provide a visual reference of movement of the corresponding placeholder needle 410. The friction ring 416 may be slidable along a diameter of the placeholder needle 410 and may be pushed against the patient's skin by the surgeon to mark the original depth of insertion.

Specification, paragraph [0020].

Thus the identification markings of the first and second placeholder elements are disclosed as color coded or numbered tags 420 as shown in Fig. 5 and it is respectfully requested that this rejection be withdrawn.

In view of the above remarks and the amendment to claim 13, it is respectfully submitted that each of claims 3, 4, 6, and 13 fully complies with §112 and it is requested that this rejection be withdrawn.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the ability of the device to access multiple sites in the tissue and the feature of the device that allows it to do so. Initially it is respectfully submitted that this claim is clear on its face -- it simply recites the device of claim 2 further comprising a second placeholder element insertable through tissue to a second selected location in a patient's body, the second placeholder element including a second element guide, the second placeholder element removably receivable in the channel." This recites merely the inclusion of the element within the claimed system and in no way recites or involves the method of operation of this system. In any case, as made clear in paragraph [0018] of the specification:

> The placeholder element 104 is placed in the tissue at the selected location for retention therein until an assessment or diagnosis of the tissue's condition has been completed and treatment is begun. In the exemplary embodiment, the placeholder element 104 comprises a placeholder needle 410 that is releasably attached to the handle element 102. Since the placeholder needle 410 is detachable from the handle element 102, *sampling at multiple sites may be carried out* by simply attaching to the handle element 102 a placeholder needle 410, placing the placeholder needle 410 at a first selected location, performing the procedure and detaching the handle element 102 from the placeholder needle 410 which is left in place in the tissue. *The process may then be repeated at a second selected location (In the treatment of prostate cancer, 6-12 locations may be needed) with a second placeholder needle 410. In this manner, the surgeon may return to the various selected locations marked by the placeholder needles 410 at a later time, to perform further diagnostics or to treat the various areas.*

That is, the operation of the second placeholder is substantially identical to that of the first placeholder. The first placeholder needle is detached from the handle element 102 and left in place. Then a second placeholder needle is attached to the handle element 102 and placed in a second location using the same procedure. For these reasons, it is respectfully submitted that claim 5 fully complies with §112 and it is respectfully requested that this rejection be withdrawn.

Claim 16 stands objected to as dependent upon a rejected base claim but has been deemed allowable if rewritten in independent form including the limitations of the base claim and any intervening claims. In view of the above amendment, it is respectfully submitted that claim 16 is in condition for allowance.

Claims 1, 8, 9, 11, 15, 17 - 18 stand rejected under 35 U.S.C. §102(b) as unpatentable over Moorman et al. (6,306,132).

Claim 1 recites a biopsy system comprising a "first placeholder element including a first lumen extending therethrough to a distal opening which, when the first placeholder element is in the first selected location is adjacent to target tissue" and "a handle including a channel extending therethrough for receiving the first placeholder element, the channel directing elements inserted thereinto to the first lumen, the handle being *removably coupled to the first placeholder element* so that the first place holder element may be left in the first selected location" and a tissue sampling element "removable from the first element guide while leaving the first placeholder

element at the first selected location" in combination with "a tissue treatment element insertable to the first selected location via the first lumen."

The Examiner stated, in support of the rejection, that the first placeholder element 10 of Moorman "has a first element guide (fig. 1)...insertable through tissue to a first location in a patient's body" and that tissue sampling element is "removable from the first element guide." However, as recited in amended claim 1, the handle is "*removably coupled to the first placeholder element* so that the first place holder element may be left in the first selected location." It is respectfully submitted that none of the references show or suggest such a removably coupled handle. Moorman describes only the electrical coupling of the delivery needle 10 and the ablation needle 35 and never describes or suggests any removable coupling between the needle 10 and any handle. In fact the handle 45 is described only as abutting the proximal port 15 of the needle 10. (Specification, col. 9, lines 6 - 11).

It is respectfully submitted therefore that Moorman neither shows nor suggests a biopsy system comprising a "first placeholder element including a first lumen extending therethrough to a distal opening which, when the first placeholder element is in the first selected location is adjacent to target tissue" and "a handle including a channel extending therethrough for receiving the first placeholder element, the channel directing elements inserted thereinto to the first lumen, the handle being *removably coupled to the first placeholder element* so that the first place holder element may be left in the first selected location" and a tissue sampling element "removable from the first element guide while leaving the first placeholder element at the first selected location" in combination with "a tissue treatment element insertable to the first selected location via the first lumen," as recited in claim 1 and that claim 1 is allowable.

Because claims 8, 9, 11, 15, 17 and 18 depend from and, therefore, include all the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 1, 3, 4, 8, 9, 12 and 14 are rejected under 35 U.S.C. §102(b) as being unpatentable over Weilandt et al. (5,788,651).

It is respectfully submitted that, similar to Moorman, Weilandt fails to show or suggest a "a handle including a channel extending therethrough for receiving the first placeholder element, the channel directing elements inserted thereinto to the first lumen, the handle being *removably*

coupled to the first placeholder element so that the first place holder element may be left in the first selected location" and a tissue sampling element "removable from the first element guide while leaving the first placeholder element at the first selected location" in combination with "a tissue treatment element insertable to the first selected location via the first lumen,"as recited in claim 1.

Specifically, the stylet 5 (analogized by the Examiner to the recited first placeholder element) is never described as removable from the assembly 1 and appears to be permanently fixed within the cannula 4 so that it can not be left in place or removed from the assembly 1. The enlarged proximal end of the stylet 5 would appear to prevent it from passing out of the cannula 4. In any case, it is submitted that there is no showing that this element is removable nor is there any indication that this would be of any use.

Thus, it is respectfully submitted that claim 1 is allowable. Since claims 3, 4, 8, 9, 12 and 14 depend from and, therefore, include all the limitations of claim 1, it is respectfully submitted that these claims are also allowable for at least the reasons stated above.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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